SPD Employee Continuing Education

Training Guides

Sterilization Methods

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STERILIZATION METHODS

INTRODUCTION

Sterilization is defined as a process by which all forms of microbial life, including bacteria, viruses, spores and fungi, are completely destroyed. It is fundamental to the operation of any SPD, surgery and invasive patient procedure. Sterilization is an absolute; gray areas cannot be accepted--it is either sterile or it is not. Selecting the method of sterilization to be used is dependent upon the heat tolerance of the item and may be divided into high temperature and low temperature sterilization.

VA Handbook 7176 lists five acceptable methods of sterilization: steam, Ethylene Oxide (EtO), Paracetic Acid, Gas Plasma, and Liquid. This inservice will explore the parameters of steam sterilization, procedures to be followed, and quality indicators.

FIRST STEP IN PROCESS

The effectiveness of any sterilization process is dependent upon the amount of bioburden on the item. Bioburden is defined as the number of microorganisms on a contaminated object. Bioburden adversely affects the sterilization process in four basic ways: 1) Some organisms have hard shells surrounding them which makes them difficult to penetrate; 2) the number of microorganisms may be in excess of the amount of steriliant required to kill them; 3) the amount and type of soil may act as a shield to protect the organism and 4) the device may have cracks and crevices in which microorganisms can hide. Therefore, the first step in the sterilization process is **proper cleaning** of all items.

Cleaning is probably the single most important step in the reprocessing sequence. If devices are not adequately cleaned, then regardless of what happens in the next operations, a sterile product cannot be consistently delivered. Cleaning procedures recommended by the device manufacturer must be followed. If the device is composed of more than one part, it should be disassembled. All jointed or hinged instruments should be opened during the cleaning process to make sure all surfaces are clean. If the cleaned agents are to be sterilized with EtO or the peroxygen plasma system, they must be thoroughly dried before packaging and sterilizing. Visible residual moisture on the device may cause the plasma-based sterilization cycle to abort.

PARAMETERS

Steam sterilization kills microorganism by causing coagulation of the protoplasm (living material found inside all cells). Saturated steam is an extremely effective “carrier” of thermal energy. Steam carries the thermal energy to the microorganism rapidly; it also acts as a softening agent for organisms with a hard shell. This process is the same as cooking foods in a pressure cooker. The steam in a pressure cooker is contained, which creates very high temperatures and intense pressure that cooks food rapidly. For steam sterilization to be effective, several conditions/parameters must be present. There must be sufficient temperature, proper time, sufficient moisture and adequate contact to all surfaces of the object.

Contact

The most frequent reason for sterilization failure is the lack of contact between steam and the microorganisms. This failure may be caused by one of these two reasons: human error or mechanical malfunction. Human error may include: failure to adequately clean the object being sterilized; packages wrapped too tightly which inhibits air removal; packages crowded on sterilization racks; containers/packages not positioned properly to allow circulation around and through all items or traps air which interferes with the sterilizer reaching proper temperature. Mechanical malfunction may result from clogged strainers, defective steam traps, clogged exhaust lines, inadequate door seals and a variety of other mechanical mishaps.

Temperature

The two most common temperatures associated with sterilization are 250°F (121°C) for gravity-displaced sterilizers and 270°F to 275°F (134°C) for pre-vacuum or dynamic air removal sterilizers. When a room temperature item is placed into a sterilizer, the steam transmits thermal energy until the item reaches the same temperature. It is at that point that exposure time is calculated. Anything that prevents all surfaces of the items being sterilized from reaching the proper temperature will adversely effect the process. The inhibitors are the same as identified in lack of contact.

Time

Thermal energy must be present for a specific period of time for the process of sterilization just as it does for cooking food. Sterilization time is measured in D-values. A D-value is the amount of time required to kill 90% of the microorganisms present. A highly resistant but relatively harmless microorganism, *Bacillus stearothermophilus,* is used to challenge hospital steam sterilizers. Hospital sterilizers are tested or challenged to provide six D-values (99.9999%), or every properly executed cycle may allow one microorganism in a million to remain viable. Since *Bacillus stearothermophilus,* is more resistant than any known pathogenic organism, a good margin of safety is provided.

Moisture

Adequate moisture content is imperative for effective steam sterilization. The steam must be saturated or have a relative humidity of 97% to 100%. Sterilizers are equipped to measure the humidity inside the sterilizer chamber. The measures are recorded in “pounds per square inch” (psi). The pressure exerted by saturated steam is constant for a given temperature and will vary in direct proportion to that temperature; that is, the higher the temperature, the higher the pressure. Steam is saturated at approximately 15 psi at 250°F and at 30 psi at 275°F.

QUALITY CONTROLS

Validating the sterilization process incorporates the use of mechanical indicators, external indicators, internal indicators and biological indicators. Mechanical indicators must be examined at the completion of each cycle. They include charts, graphs or digital displays to record the various functional or the machine. External indicators must be inspected prior to the application of load control label. They give visual validation that the package was exposed to the steriliant. Internal indicators are placed inside each sterilized item. Internals indicators are optional and tell the users that conditions of sterilization were present in the center of the package and gives relative assurance of sterilization. Biological indicators are designed to monitor the efficacy of the sterilization process. They serve to demonstrate that conditions necessary for sterilization were achieved. A biological indicator must be run daily on all steam sterilizers, in each load containing an implant and each ETO load. The BI must be incubated for 48 hours before the load is released.

AIR REMOVAL TESTS

A Bowie-Dick test is done daily on all pre-vacuum steam sterilizers to determine adequacy of air removal from the chamber. Since air removal is paramount to the attainment of the proper temperature and can interfere with the steam contacting the item, it is imperative that this test is done daily. The test is run in an empty load and must be run before the first processed load of the day. Pre-packaged test packs are available and give the greatest consistency of results. They should be placed in the area that provides the greatest challenge.

All sterilization records must be meticulously maintained for a period of 36 months.

LOW TEMPERATURE STERILIZATION

These methods are specifically designed to sterilize items that are heat sensitive, will not tolerate high temperatures or pressure. The most commonly used is Ethylene Oxide (EtO), a toxic, carcinogenic agent which requires a prolonged sterilization and aeration process. Within the last several years, new methods have been developed such as gas plasma (Sterrad) and liquid point of use (Steris), which allows for a rapid sterilization process.

In order for low temperature sterilization to be effective, several requirements must be met:

1. Effectiveness – The steriliant must provide good microbial kill against a wide range of microorganisms.
2. Safety – There should be no toxic steriliant residuals remaining on the packaging or device. (Not pose a safety hazard to healthcare workers or patients.
3. Penetration – The steriliant must penetrate through all packaging systems and provide contact with all surfaces.

4. Material compatibility – There should be no changes in the functionality of the device.
5. Monitoring – The process should be capable of being reliably monitored with readily available mechanical, chemical and biological indicators.
6. Adaptability – The process should be compatible with or easily modified to meet existing healthcare practices.
7. Approval – The sterilization system must be cleared by and registered with the appropriate regulatory agencies.

ETHYLENE OXIDE

EtO gas has been the predominate choice for low temperature sterilization since the 1960s. EtO has excellent product penetration and material compatibility. EtO is an alkylating agent, increases the pH greater than 7, which reacts with the DNA of the microorganism and destroys the cells' ability to metabolize or reproduce. It is supplied in three basic forms for hospital based sterilization, 10% EtO and 90% hydrochlorofluorocarbon (HCFC), 8.6 % EtO and 91.4% carbon dioxide and 100% EtO. Because EtO in the 100% state is extremely flammable, it must be stored and used in small chambers usually 4 to 8 cubic feet. Blended EtO is not flammable and is supplied in large cylinders. 70% of EtO used by hospitals are of the blended nature. Ethylene oxide users must comply with the special OSHA guidelines in 29 CFR 1910.1047.

Efficacy of kill is measured in Sterility Assurance Levels (SALs); for Ethylene Oxide it is 10^6 or 99.9999%. To test efficacy, a highly resistant *Bacillus Subtilis* is used to challenge each sterilization load. Because it is imperative that the EtO penetrates the packaging and contacts all surfaces of the item, Biological indicators impregnated with *B Subtilis* are placed in each load.

Despite the effectiveness of EtO, several undesirable drawbacks have made it less popular in hospital sterilization. EtO is a colorless, odorless (in concentrations below 500 Parts Per Million or PPM) toxic gas. It is classified as a mutagenic, carcinogenic and reproductive hazard; therefore strict adherence to OSHA guidelines relative to employee safety must be followed. Exposure levels set by OSHA are; Action level is set at **0.5ppm**, 8-hour exposure limit is **1 PPM** and the short-term exposure limit (STEL) or 15 minutes is limited to **5 PPM**. EtO sterilizers must be located in a well-ventilated area with a minimum of 10 air changes per hour. It must have an adequate exhaust and ventilation system, including floor drains to prevent any escape of EtO into the workplace.

Facilities using EtO must monitor the work area for release of the gas. Personnel monitoring systems that provide immediate notification are required to meet current standards. A written exposure plan, written emergency action plan, and evidence of employee training are all mandatory. Periodic environmental sampling is not required unless release of EtO rises above the acceptable levels.

GAS PLASMA

The use of gaseous peroxygen compounds, especially hydrogen peroxide, for sterilization was developed in the 1990's. The hydrogen peroxide plasma sterilizing system is cleared for use with both metallic and non-metallic medical devices that are packaged in non-woven polypropylene wrappers or specific plastic containers. No lumens with an internal diameter of less than 3 mm (1/8 inches) or devices greater than 30 cm (16 inches) can be processed in the sterilizer. Additionally, cellulosic materials, including paper and textiles, powders, liquids and devices with dead-end lumens are not indicated for sterilization using plasma.

Several differences exist between EtO and the new Plasma sterilization processes. The most significant is that the plasma does not employ chemicals that are carcinogens, mutagens or reproductive hazards. Secondly, they do not require long aeration cycles or leave toxic residues that mandate special handling. Hydrogen peroxide is a strong oxidizing agent and is irritating to the skin, mucus membranes and eyes; the Sterrad® system uses a contained exposure system that reduces potential exposure. The vials of steriliant are not pierced until the access door is closed. When a set of cartridges is complete, the entire set drops into a locked drawer inside the machine. OSHA has established 8-hour exposure levels for hydrogen peroxide at 1.0 ppm but does not require employee monitoring. It is extremely unlikely that employees could be exposed to this level due to the fact that the concentration of hydrogen peroxide is very low and it readily breakdowns into nontoxic entities.

The plasma-based system must draw a very deep vacuum of1 torr or below (torr is a unit of pressure: 1 torr=1/760 atmosphere) compared to EtO's 50 torr or above. Once the deep vacuum is attained, a pre-set amount of H_20_2 is injected.

Packaging materials also affect the penetrating capability of the sterilant. Cellulosic-containing packaging materials such as paper-plastic peel pouches, disposable wrappers and muslin are incompatible with the hydrogen peroxide process because they absorb the peroxide and do not allow effective penetration. Metal containers, paper count sheets and most protective foam cannot be used in the chamber of the Plasma sterilizer. Special Tyvek® peel-pouches approved plastic containers and protective foam must be purchased.

Complete plasma cycles are approximately 72 – 90 minutes as compared to 15 hours to 18 hours in the EtO sterilizers. This makes plasma sterilization very attractive where expensive, heat-sensitive items are required throughout the day thereby reducing the quantities and capital outlay.

Items approved for sterilization in Hydrogen Peroxide Plasma sterilizers include:

1) Metallic and non-metallic medical devices, packaged in non-woven polypropylene barrier material (i.e. Tyvek/Mylar pouches or Spunguard wrappers);
2) Medical devices with lumens with a inner diameter of at least 3 mm (1/8 inch).

These sterilizers challenge each load with spores of *Bacillus subtilis*, inoculated strips that must be transferred after coming in contact with the steriliant. Once a neutralizing agent is added to stop the oxidizing process, these strips are incubated for 48 hours.

PERACETIC ACID (PAA)

Peracetic acid (PAA) sterilization has limited usage in the healthcare arena. It is used primarily for immersible medical instruments including flexible and rigid endoscopes that require sterilization between cases. Liquid peracetic acid is a highly effective anti-microbial agent that is effective against gram-positive and gram-negative bacteria, fungi and yeast in five minutes. PAA is a clear, colorless solution with a pungent odor and is a strong oxidizing agent that has excellent material compatibility. Penetration is not an issue with PAA since it is a liquid and the items are not wrapped. It only requires that all pathways are open so that liquid comes in contact with all surfaces. However, items sterilized with peracetic acid are not maintained sterile once they are removed from the sterilant, as they are not packaged; therefore, they are best designed to be utilized at the point of use.

In the liquid peracetic acid process, the key parameters are sterilant concentration, temperature and time. The process time is approximately 30 minutes at temperature range of 50°-56° C. Biological indicators for PAA are inoculated with *Bacillus stearothermophilus*.

The OSHA permissible exposure limit for acetic acid is 10 PPM. The use dilution of the PAA in the system is 0.2%. The system is equipped with a concentration sensor. If the dilution drops below this predetermined concentration, the machine will fail.

LIQUID CHEMICAL STERILIZATION (GLUTARALDEHYDE, PHENOLIC COMPOUNDS, ALCOHOLS, QUATS, AND IODINE)

According to VA Handbook 7176, no liquid chemical sterilization is authorized because the efficacy of the process cannot be validated. These solutions may be employed for high-level disinfection only.

OBJECTIVES
METHODS OF STERILIZATION

1. Define the sterilization methods for medical devices approved by VA Handbook 7176.

2. Identify components necessary to ensure adequate sterilization.

3. Recognize parameters necessary to achieve sterilization.

4. Identify types of indicators used to validate sterilization.

5. Verbalize understanding of the temperature/pressure relationship.

POST TEST
METHODS OF STERILIZAION

1. Identify the methods of sterilization approved by VA Handbook 7176.
   a. EtO, steam, liquid & PA
   b. steam, plasma, EtO & PA
   c. PA, liquid, steam & plasma
   d. None of the above

2. Steam sterilizer efficacy is challenged by
   a. Bacillus Stearothermophilus
   b. Bacillus Circulans
   c. Bacillus Subtilis

3. EtO is used synomonously with:
   a. Gas
   b. plasma
   c. Steris
   d. liquid

4, The most commonly used and cost effective method of sterilization is:
   a. Ethylene oxide
   b. Plasma
   c. Steam
   d. Peracetic acid

5. Steam sterilization kills microorganisms by:
   A. coagulation
   B. oxidation
   C. alkalosis

6. The most frequent reason for sterilization failure is:
   a. poor wrapping technique
   b. inadequate contact with all surfaces
   c. sterilizer malfunction
   d. none of the above

7. The first step in the reprocessing procedure is_______ __________.

8. Ethylene Oxide is the most commonly used sterilization process for ______ ___________ items.

9. Bioburden is defined as the number of _____________ on contaminated items.

10. ___________ and _____________ are two components necessary for effective steam sterilization.

ANSWER KEY

METHODS OF STERILIZATION

1. B
2. A
3. A
4. C
5. A
6. B
7. proper decontamination
8. heat sensitive
9. microorganism
10. temperature & pressure